fish containing nematode larvae that are dead or devitalized following appropriate treatment is dangerous to human health.

Since the Agreement between the European Economic Community and the Kingdom of Norway contains, with respect to trade between the Contracting Parties, rules identical with those laid down in Articles 30 and 36 of the Treaty and there is no reason in the present case to interpret them differently from those articles of the Treaty, the national measures referred to above also constitute, with respect to consignments of fish from Norway, a failure to fulfil the obligations under Regulation No 1691/73 concluding the said Agreement and adopting provisions for its implementation.

The systematic inspection of consignments certified free from live larvae also constitutes a failure to fulfil the obligations under Directive 83/643 on the facilitation of physical inspections and administrative formalities in respect of the carriage of goods between Member States.

REPORT FOR THE HEARING
in Case C-228/91 *

I — Legal framework, facts and pre-litigation procedure

1. (a) In Italy, Article 11 of Law No 125 of 25 March 1959 (GURI 1959, No 87, p. 1294) provides as follows:

'In markets in fishery products, a service responsible for health inspection and monitoring species and categories of goods shall be established under the general control ... of a specialist veterinary surgeon appointed by the local municipality ... fishery products from other municipalities, even if they are the subject of contracts concluded outside the market, and likewise fishery products intended for preserving, shall still be required to undergo a health inspection in accordance with the detailed rules laid down by the provincial health authorities'.

That provision is specified by Article 11 of the Ministerial Order of 10 June 1959, under which

'Fishery products landed or coming from other countries or municipalities ... must invariably have been submitted to a health inspection ...'.

* Language of the case: Italian.

(b) In accordance with the first paragraph of Article 1 of Law No 283 of 30 April 1962 (GURI 1962, No 139, p. 2194), as amended by Law No 441 of 26 February 1963 (GURI 1963, No 98, p. 1935) and Decree No 777 of the President of the Republic of 23 August 1982 (GURI 1982, No 298, p. 7808),

'The production and marketing of foodstuffs shall be monitored to ensure the protection of public health. To that end, the health authorities may proceed at any time, through the competent bodies and services, to carry out inspections and take samples in public undertakings and establishments where foodstuffs are produced, stored, marketed or consumed, and also in ports of call and means of transport. They may also seize and destroy goods if their investigations indicate that it is necessary for the protection of public health.'

The fifth paragraph of that article states that the traders concerned may submit an 'application for a review' of results of analyses unfavourable to them, within 15 days of receiving notification of those results. If they do not submit an application for a review within the prescribed period or if the second analysis confirms the results of the first, the provincial medical officer or veterinary surgeon must lodge a complaint with the judicial authorities within fifteen days.

Article 5 of Law No 283 of 30 April 1962 provides that

'It is prohibited to use in the preparation of foodstuffs or beverages, sell, hold with a view to selling, supply ... or distribute for consumption, foodstuffs which:

(a) lack, even in part, their nutritive elements and are mixed with substances of lower quality ...,

...

(d) are contaminated, infested with parasites, spoilt or harmful, or which have undergone treatment designed to mask earlier impairment'.

Under Article 12 of that Law,

'It is prohibited to introduce into the territory of the Italian Republic any substance intended for human consumption which does not satisfy the requirements laid down by this law'.

Article 16 of the Law states that

'If it finds that substances of any kind intended for human consumption are harmful, the health authority shall order them to be seized and destroyed, unless it decides to authorize their use for purposes other than human consumption',

whilst Article 17 provides for fines to be imposed on persons contravening the prohibition set out in the aforementioned Article 5.

(c) Whilst some powers in the area of veterinary inspection and foodstuffs monitoring have been devolved to the regions and the municipalities, the Italian State has retained for its own departments all functions pertaining to international relations and Community obligations. Thus, Law No 833 of 23 December 1978 (GURI 1978, No 360, supplement, p. 3), establishing the national health service, lays down the principle that the State must 'ensure uniform health conditions and guarantees throughout the national territory' in the matter of food and drink hygiene. Consequently, all the administrative functions pertaining to 'international prophylactic measures, including veterinary measures, at sea, in the air and at frontiers', as well as the task of laying down quality and hygiene criteria for foodstuffs and beverages, fall within the exclusive competence of the Italian State.

(d) Presidential Decree No 327 of 26 March 1980 (GURI 1980, No 193, p. 6043), which implements the aforementioned Law No 283 of 1962, as amended on several occasions, provides that the Ministry of Health, on the one hand, acting through its own central bodies, the air and sea health services and the veterinary services at frontiers, in ports, airports and customs posts, and the regional and municipal authorities, on the other, acting in so far as they are competent to, through local health units, may proceed at any time to carry out inspections and take samples of products intended for human consumption in establishments, warehouses, stores, shops and markets, and may also inspect and take samples of imported goods on arrival at their destination or when they are presented for customs clearance.

Under Presidential Decree No 254 of 8 May 1985 (GURI 1985, No 138, p. 4165), which is intended to implement Council Directive 83/643/EEC of 1 December 1983 on the facilitation of physical inspections and administrative formalities in respect of the carriage of goods between Member States (OJ 1983 L 359, p. 8), health inspections of products of animal origin are to be carried out by means of spot checks. This principle applies both to products from other Member States and to those from third countries but, whereas products in the first category must be accompanied by a certificate of origin and a health certificate, those in the second category must be inspected by taking samples from all shipments.

With regard to the rules on inspection by means of spot checks, Article 3(1)(b) of Ministerial Order No 454 of 8 October 1988 (GURI 1988, No 253, p. 7), as amended by Ministerial Order No 47 of 15 February 1990 (GURI 1990, No 61, p. 3), provides that, in the case of edible products of animal origin, at least 10% of the consignments presented or expected to arrive within any one week must be subjected to health checks. Under the fourth paragraph of that article, the proportion inspected

'shall be increased if, in the opinion of the veterinary surgeon at the frontier or the Ministry of Health, there is any doubt or if precautions need to be taken to protect public or animal health'.

As regards more specifically health inspections of imported fishery products, these are carried out pursuant to Articles 2 and 3 of Presidential Decree No 254 of 1985 by the frontier veterinary services, which are required to examine the certificates of origin and health certificates and effect the necessary checks. Spot checks are to be carried out in such a way that, over a period defined in relation to the nature and density of the traffic, inspections cover all the countries and, within each country, all the administrative districts of origin, all the production establishments or warehouses of origin and all the consignees of the products. The health inspection of the consignments selected for spot checks may be carried out, on the advice of the frontier veterinary surgeon, on all or part of each consignment.

(e) Article 72 of Presidential Decree No 327 of 1980 provides that

'Importers of foodstuffs shall be responsible for the nature, type, quantity, uniformity and origin of the products presented for importation, and for ensuring that the health and hygiene requirements laid down in the current food regulations are met'.

In addition, the Italian Criminal Code lays down penalties for 'any person who holds with the intention of marketing or distributes for human consumption foodstuffs which, without being disguised or modified, constitute a danger to public health' (Article 444) or who 'offers for sale or in any other way markets as natural foodstuffs which are not natural' (Article 516). Article 444 has been interpreted by the Italian Corte di Cassazione (Court of Cassation) as meaning that not all the goods marketed need be harmful; on the contrary it is sufficient for a significant quantity of them to be harmful, if the substance is capable of damaging public health (judgment of 30 September 1964).

2. (a) Council Regulation (EEC) No 3796/81 of 29 December 1981 on the common organization of the market in fishery products (OJ 1981 L 379, p. 1), as amended, covers practically all fishery products and includes rules on prices and trade with third countries. Article 4 of the regulation sets out the following principle:

'Products for which common marketing standards have been adopted shall be liable to inspection by Member States for conformity with those standards'.

(b) Council Regulation (EEC) No 103/76 of 19 January 1976 laying down common marketing standards for certain fresh or chilled fish (OJ 1976 L 20, p. 29), as amended, notably by Council Regulation (EEC) No 33/89 of 5 January 1989 (OJ 1989 L 5, p. 18), applies to a great many varieties of fish, including herring, cod and mackerel. The third paragraph of Article 5 provides that

'On the basis of the freshness ratings in Annex A, fish shall be classified by lot in freshness categories "Extra", A or B'.

Pursuant to Article 6(5),

'For the purpose of classifying products into the various freshness categories, without prejudice to the applicable health rules, account shall also be taken of the presence of parasites and any adverse effect they may have on the quality of the products having regard to their nature and presentation'.

'Each lot must contain products of the same degree of freshness' and 'the freshness category must be clearly and indelibly marked, in characters which are at least 5 cm high, on labels affixed to the lot' (Article 7(1) and (2)). The same principles apply to fish from third countries (Article 10).

(c) Directive 83/643, as amended by Council Directive 87/53/EEC of 15 December 1986 (OJ 1987 L 24, p. 33) and Council Directive 91/342/EEC of 20 June 1991 (OJ 1991 L 187, p. 47), lays down the principle that inspections must be carried out 'by means of spot checks, except in duly justified circumstances' (Article 2(1), second indent). Article 9 of the directive provides as follows:

'Where, in exceptional and justified cases, a Member State intends to introduce a new inspection or formality, it shall inform the Commission thereof.

The Member State concerned shall ensure that the measures taken to facilitate the crossing of frontiers are not rendered inoperative through the application of such new inspections or formalities'.

(d) Council Regulation (EEC) No 1691/73 of 25 June 1973 (OJ 1973 L 171, p. 1) concludes an Agreement between the European Economic Community and the Kingdom of Norway and adopts provisions for its implementation.

Article 13(1) of that agreement, which is annexed to Regulation No 1691/73, lays down the principle that

'No new quantitative restriction on imports or measures having equivalent effect shall be introduced in trade between the Community and Norway'.

Under Article 20 of the agreement,

'prohibitions or restrictions on imports, exports or goods in transit justified on grounds of ... the protection of life and health of humans, animals or plants ... must not ... constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties'.

Article 15(2) of the agreement provides that

'The Contracting Parties shall apply their agricultural rules in veterinary, health and plant health matters in a non-discriminatory fashion and shall not introduce any new

measures that have the effect of unduly obstructing trade'.

Article 22(1) provides that

'The Contracting Parties shall refrain from any measure likely to jeopardize the fulfilment of the objectives of the Agreement'.

(e) Finally, the Commission cites

— Commission Directive 70/50/EEC of 22 December 1969 based on the provisions of Article 33(7), on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty (OJ, English Special Edition 1970 (I), p. 17), which, however, is no longer in force;

— Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (OJ 1989 L 186, p. 23), which is intended to harmonize inspections of foodstuffs other than those carried out at the frontier;

— Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ 1989 L 395, p. 13); however, the period prescribed for implementing this directive had not yet expired when the present action was brought;

— the proposal for a Council Regulation (EEC) laying down health conditions for the marketing of fish and fish products concerning nematodes, submitted by the Commission on 22 February 1988 (OJ 1988 C 66, p. 2) and amended on 18 September 1989 (OJ 1989 C 282, p. 7), which authorizes the marketing of fish containing nematodes, provided that it has undergone special treatment (heating to a temperature of not less than +70°, salting, marinating or freezing at a temperature of -20°), and specifies that consignments of fish products which are the subject of intra-Community trade must be accompanied by a document certifying that they have been treated;

— the Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 ('Cassis de Dijon') (OJ 1980 C 256, p. 2), and

— the Commission Communication on the free movement of foodstuffs within the Community (OJ 1989 C 271, p. 3).

3. (a) Following a German television broadcast in July 1987, which purportedly gave an exaggerated, inaccurate account of the dangers to public health caused by the presence in fish of nematode larvae of the 'anisakis' variety, the Commission received a number of complaints, particularly from Denmark and Norway and from wholesalers exporting fish and fish products principally to Italy.

(b) The complaints alleged that in July 1987 Italy had introduced new frontier inspection measures for fish and fishery products which resulted in serious restrictions of intra-Community trade and trade between Italy and Norway in the products concerned.

Imported fishery products, particularly mackerel, herring, whiting and hake, were subjected to systematic inspection — even if the consignments in question had been inspected before dispatch and were accompanied by health certificates — and were turned back or even destroyed if a single larva was found, even devitalized. It was alleged that at one point those measures had made it completely impossible to export the products in question to Italy and the traders concerned had incurred serious financial losses as a result.

4. (a) Following those complaints, the Commission found that from July 1987 Italy had applied a stricter system of health inspections to imported fish and fishery products, mainly affecting fresh, frozen or smoked mackerel, herring, salmon and hake imported from Member States and third countries.

The purpose of those inspections, which were carried out by the frontier veterinary services, was to turn back fish products in which nematode larvae had been detected.

(b) It appears from a note attached to a letter to the Commission from Italy's Permanent Representative to the European Communities, dated 13 March 1989, that those inspections were prompted by telegrams sent by the Italian Ministry of Health to the frontier veterinary services pursuant to Law No 283 of 1962 with a view to applying stricter controls to fishery products on importation because the Italian authorities had noted an increase in the number of consignments infested with larvae and in the number of parasites in consignments.

The first telegram, dated 18 July 1987, introduced systematic inspection of chilled or frozen mackerel on importation. A further telegram of 4 September 1987 extended those inspections to fresh, frozen and smoked herring, salmon and cod. A telegram dated 14 October 1987 extended the inspections for nematode larvae to Italian fishery products, essentially whiting, bogue, mackerel, monkfish, sardines, anchovies, red mullet and sea bream. Lastly, a telegram dated 15 December 1987 authorized inspection by means of spot checks on frozen mackerel, herring and cod, provided that the fish was accompanied by health documents certifying that the product had been kept at a temperature of -20° for at least 24 hours, and on fresh, frozen or smoked salmon.

(c) The Commission states that in 1987 1 725 consignments of fishery products imported from Member States and 466 consignments imported from third countries, representing 4.3% and 11.5% respectively of the total amount of fish imported into Italy from those sources, were inspected. 134 consignments from Member States and 17 from third countries were turned back on the ground that they were infested with nema-

todes. In the case of Norway, 21 consignments were inspected and 6 turned back.

According to the Commission, the inspections were even more rigorous in the case of some Member States. Thus, more than 20% of imports from the United Kingdom and 30% of imports from the Netherlands were inspected in 1987. In 1988, more than 40% of imports of fish from the Netherlands were inspected. The incidence of health inspections was even higher in the case of some species of fish, such as mackerel and herring, and Italy carried out very thorough inspections of salmon and whiting, despite the fact that the problem of nematodes is not so acute in their case.

5. (a) The Commission considered that it was clear from the national provisions and the abovementioned facts that the Italian Republic required fish to be completely free from nematodes, dead or alive, and prohibited the importation and marketing of consignments in which nematodes had been found. From 1987, with a view to seeking nematode larvae, the Italian Republic introduced new measures for the health inspection of fish and fishery products on importation from other Member States and third countries which far exceed the admissible limits for spot checks and apply to consignments that comply with the legislation of the State of origin and are accompanied by duly completed health certificates.

In view of the fact that the presence of nematodes in fishery products is not a new phenomenon and that such parasites are also present in fish caught by Italian vessels and landed in that Member State, the Commission considered that the Italian Republic had failed to fulfil its obligations under Community law inasmuch as the measures described above constituted measures having equivalent effect to quantitative restrictions on imports and exceeded that which was necessary to protect human health. The Commission also considered that the systematic inspection of the products concerned at the frontier was not proportionate to the aim to be achieved and unduly restricted trade between Member States and with Norway.

The Commission therefore wrote to the Italian Government on 28 December 1988 giving it formal notice, in accordance with Article 169 of the EEC Treaty, to submit its observations on the alleged failure to fulfil its obligations within one month.

(b) By letters dated 13 March and 7 September 1989, the Italian Government replied that under its legislation, which prohibited the supply for human consumption of foodstuffs which were infested with parasites or deprived, even partly, of their nutritive elements, the presence of nematodes, even dead ones, in fish constituted a qualitative and quantitative change in the composition of the product in question, irrespective of the level of infestation and of whether the fish was fresh, frozen, smoked, dried or salted. The Italian Government added that the health inspection of fishery products was applied without distinction to domestic products and to imports from other Member States and third countries alike and that there was no specific Community legislation on the subject. Lastly, it contended that there were no detailed scientific studies on the toxicity of nematodes in fish.

(c) Considering the Italian Government's reply to be unsatisfactory and legally incorrect, the Commission delivered a reasoned opinion, pursuant to the first paragraph of Article 169 of the EEC Treaty, on 2 July 1990, to the effect that by prohibiting the importation of fish from other Member States and Norway and requiring such consignments of fish to undergo systematic inspections, the Italian Republic had failed to fulfil its obligations under Articles 30 and 36 of the EEC Treaty, inasmuch as they formed an integral part of Regulation No 3796/81, Directive 83/643/EEC and Regulation No 1691/73.

The Commission requested the Italian Republic, pursuant to the second paragraph of Article 169 of the EEC Treaty, to take the necessary measures to comply with the opinion within two months.

(d) The Italian authorities did not respond to the reasoned opinion.

II — Written procedure and forms of order sought

1. By application lodged at the Court Registry on 11 September 1991, the Commission brought an action before the Court under the second paragraph of Article 169 of the EEC Treaty for a declaration that the Italian Republic had failed to fulfil its obligations under Articles 30 and 36 of the EEC Treaty, inasmuch as they formed an integral part of Regulation No 3796/81, Directive 83/643/EEC and Regulation No 1691/73.

2. Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry. The Commission was asked to answer a question in writing and did so within the prescribed period.

3. The *Commission*, the applicant, claims that the Court should:

— declare that, by prohibiting in practice, on the basis of national legislation which is applicable without distinction, and of the corresponding specific administrative measures for its implementation, the importation of consignments of fish from the other Member States and from the Kingdom of Norway solely on the ground that they contain nematode larvae, and by requiring such consignments to undergo systematic inspections, the Italian Republic has failed to fulfil its obligations under Articles 30 and 36 of the EEC Treaty, inasmuch as they form an integral part of Council Regulation (EEC) No 3796/81 of 29 December 1981 on the common organization of the market in fishery products, Council Directive 83/643/EEC of 1 December 1983 on the facilitation of physical inspections and administrative formalities in respect of the carriage of goods between Member States, and Council Regulation (EEC) No 1691/73 of 25 June 1973 concluding an Agreement between the European Economic Community and the Kingdom of Norway;

— order the Italian Republic to pay the costs.

4. The *Italian Government*, the defendant, contends that the Court should:

— dismiss the Commission's application;

— order the Commission to pay the costs.

III — Pleas and arguments of the parties

1. (a) In its application, the *Commission* first explains that the infestation of fishery products with nematode larvae of the 'anisakis' variety, which develop and multiply in the intestines of large marine mammals, is a natural phenomenon associated with the marine food cycle and is not attributable to external causes such as water pollution.

Those parasites, which affect mainly herring, mackerel, sprats and hake, are present in all the Community fishing zones, including Italian waters.

As to any harm that might befall humans as a result of eating fish containing nematodes, live larvae, although they are to be found only in fish that is consumed raw or lightly salted, smoked or marinated, as is the custom in Japan and to a lesser extent in the Netherlands, can cause a serious disease in man, known as 'anisakiasis', which is rather difficult to diagnose. However, that disease is extremely rare in the Member States because of the eating habits prevalent in those countries, since any larvae in the fish are killed when it is cooked. Anisakiasis has been virtually eliminated in the Netherlands by a law requiring herring to be frozen.

Live larvae can also be devitalized by simple, inexpensive and widely used processes, such as cooking at a temperature of not less than +60° for at least two minutes, freezing at a temperature of not more than -20° for at least 24 hours, marinating by immersing the fish for a specified period in a solution having a high pH and a suitable salt concentration, possibly in combination with other preservatives, or salting in a minimum 20% sodium chloride solution for at least twenty days. Smoking presents a certain risk if the temperature is too low or the smoking process is too short. Gutting is satisfactory only if the fish is gutted and carefully washed immediately after it is caught but fillets may still contain live larvae.

On the other hand, the findings of modern scientific research show that dead larvae (either in raw fish or in cooked or processed fish, where the system of neutralization has killed them) are quite harmless to human health, with the result that the products in question can be marketed and consumed freely, even in the raw state. Also, the presence of dead larvae does not alter the organoleptic characteristics of the fish and does not usually entail any risk to the presentation of the foodstuff. Lastly, the consumer is protected inasmuch as the consumption of fish containing dead nematodes does not cause allergic reactions or symptoms of

rejection. Moreover, there is nothing to prevent Member States from taking measures to warn consumers that a particular consignment of fish is infested with dead larvae or to classify that consignment in a lower freshness category than usual in accordance with the provisions of Regulation No 103/76.

The Commission adds that its point of view is confirmed by the international rules recognized by the Codex Alimentarius Commission under the joint FAO/WHO programme on the food standards applicable to deep-frozen fillets of certain species of fish, from which it appears that the presence of nematodes does not in itself justify the view that the products in question are defective or unacceptable.

The Commission therefore concludes that the Italian authorities are not justified in considering that there is a risk to human health both from consignments of fish infested with live nematodes and from those containing dead ones, with the risk of toxicity increasing in proportion to the number of dead larvae, and that the presence of even very small quantities of nematodes in fish means that it is contaminated and consequently must be assumed to represent a danger to human health on the ground that the fact that the fish is infested with nematodes, even dead ones, means that it has lost its biological value, if only to some extent.

In the first place, the consumption of raw fish is extremely rare in Italy and anisakiasis is now practically non-existent in that Member State with the result that any special protection of public health is unnecessary. In the second place, modern scientific findings confirm that fish infested with dead nematodes is not toxic and there is consequently no proof that ingestion of dead larvae, even in large quantities, is harmful to human health.

(b) The Commission adds that the Italian Republic has infringed Community law by freely interpreting national legislation which is applicable without distinction and applying it strictly by means of *ad hoc* administrative measures, thus in practice prohibiting the importation of consignments of fish from the other Member States and from Norway solely on the ground that the fish contains live or dead nematode larvae, irrespective of quantity, since the presence of even one larva might be enough, and by requiring such consignments to undergo systematic inspections at the frontier.

— In the first place, the Commission considers that the Italian Republic has failed to fulfil its obligations under *Articles 30 and 36* of the EEC Treaty, which form an integral part of *Regulation No 3796/81*.

In this connection, the Commission submits, first, that the inspections implemented by the Italian authorities constitute measures having equivalent effect to quantitative restrictions on imports. The Court has consistently held that 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade' are to be considered

as such (Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5).

It takes the view that, by prohibiting in practice the importation of fishery products infested with nematodes, even dead or in very small quantities, and by imposing systematic inspections at the frontier, the Italian Republic is hindering the importation of products from other Member States which comply with the health regulations of those States.

The Commission states that in this case the Member State's legislation is applicable to domestic and imported products without distinction and is therefore in principle lawful, in the absence of any Community legislation on fish products infested with nematode larvae. However, the Court has held that measures of this kind must not obstruct intra-Community trade more than is necessary in order to satisfy mandatory requirements (Case 120/78 *Rewe-Zentral* v *Bundesmonopol für Branntwein* ('Cassis de Dijon') [1979] ECR 649, paragraph 8).

Given that in this case the Italian Government has invoked the protection of health, mentioned in Article 36 of the EEC Treaty, it must be borne in mind that that provision can be relied upon to justify restrictions on imports only if they do not constitute a disguised restriction of intra-Community trade. In this connection, the Court held in Case 104/75 *De Peijper* [1976] ECR 613, paragraphs 16, 17 and 18, that national rules or practices capable of having a restrictive effect on imports are only compatible with the Treaty to the extent to which they are necessary for the effective protection of health and life of humans and therefore do not fall within the exception specified in Article 36 if that imperative can be as effectively protected by measures which do not restrict intra-Community trade so much.

The Commission considers that the restrictive Italian measures do not satisfy those requirements.

In the first place, it claims that the measures in question are not essential for the protection of human health, since the health risk that they seek to avoid is extremely limited and affects a very small number of people. The infestation of fish with nematodes of the 'anisakis' variety is a natural, widespread and more or less unavoidable phenomenon. Moreover, only live larvae present a risk to human health and then only if fish is consumed raw, while dead nematodes are not toxic. That being so, bearing in mind eating habits in Italy, where the consumption of raw fish accounts for only an extremely small proportion of the market, the very strict Italian health inspections are manifestly excessive, as they entail turning back products from the other Member States and Norway which contain only dead nematodes, and those in very small quantities, and in practice prevent the importation of fish into Italy.

In the second place, it claims that the restrictions are not irreplaceable. Instead of turning consignments of fish back at the frontier or ordering them to be destroyed, there is a broad range of alternative measures that would enable the same results to be achieved with less serious damage to traders. For example, there are simple and inexpensive

ways of treating fish, such as cooking, freezing, smoking, salting or marinating, which would preclude any possible health risk. Moreover, not all consignments of fish are intended for the final consumer; many are destined for the processing industry and will therefore inevitably undergo some form of processing.

The Commission therefore suggests the following measures as an alternative to those adopted in Italy.

In the case of fish containing live larvae, it would be sufficient for the Italian authorities to prohibit such fish to be eaten raw, require it to undergo suitable treatment before marketing, or restrict its use to the processing industry. If fish contains dead larvae, it should be released for consumption unconditionally, possibly with an appropriate warning to the consumer, with whom the decision would ultimately lie as to whether to buy it.

In this connection, Regulation No 103/76 allows for fish containing parasites such as nematode larvae by stipulating that this should be taken into account for the purpose of classifying products into various freshness categories which are to be clearly marked on labels affixed to the lots, but does not prohibit the marketing of such fish.

The Commission adds that the systematic health inspections carried out in Italy on consignments of fish accompanied by health certificates issued by other Member States and Norway are manifestly incompatible with Article 30 of the EEC Treaty, since the legislation of those States fully guarantees the good quality of the fish and precludes any risk to human health arising as a result of the presence of nematode larvae.

It follows from paragraph 14 of the judgment in Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Producten* [1981] ECR 3277 that, in order to assist in bringing about a relaxation of the controls existing in intra-Community trade, Member States are not entitled to carry out systematic health inspections of goods on importation where such inspections have already been carried out in the Member State of dispatch and the results of the inspections are recorded in health certificates issued by the authorities of that State. Only spot checks are allowed in such cases, to verify that the certificates are accurate and in order to prevent fraud. A 'double-check' in the exporting country and in the importing country is contrary to the principle of mutual trust between the health authorities of the Member States and mutual recognition of the results of tests and analyses if health requirements may be satisfied as effectively by measures which are not so restrictive of intra-Community trade (Case 251/78 *Denkavit Futtermittel* [1979] ECR 3369 and Case 132/80 *United Foods* [1981] ECR 995, paragraph 29).

According to the judgments in Case 174/82 *Sandoz* [1983] ECR 2445, paragraph 18, and Case 25/88 *Wurmser* [1989] ECR 1105, paragraph 18, the principle of proportionality which underlies the last sentence of Article 36 of the Treaty requires that the

power of the Member States to prohibit imports of products from other Member States should be restricted to what is necessary to attain the legitimate aim of protecting health.

The Commission considers that the Italian measures at issue in this case are not proportionate to the aim of protecting health, since the Italian authorities could have adopted instruments that guaranteed the same degree of health protection but were more in keeping with the principle of the free movement of goods. The irrebuttable presumption applied by the Italian Government that nematodes are toxic is not only inconsistent with the findings of scientific research but also contrary to the case-law of the Court (Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraphs 39 and 40), according to which it is for the national authorities to demonstrate that their rules are necessary to give effective protection to the interests referred to in Article 36 of the Treaty and, in particular, to show that the marketing of the product in question creates a serious risk to public health.

Similarly, it is clearly stated in the Commission's Communication of 24 October 1989 on the free movement of foodstuffs within the Community (cited above) that the importation and marketing of foodstuffs lawfully produced and marketed in another Member State may be restricted, in the absence of harmonized rules at Community level, only where such a measure can be demonstrated to be necessary in order to satisfy mandatory requirements, is proportionate to the desired objective and is the means of achieving that objective which least hinders trade.

The Commission therefore considers that the restrictive Italian measures are prohibited by Article 30 and cannot be justified under Article 36, since they are not based on scientific grounds that render them necessary or irreplaceable and are therefore disproportionate in relation to the objective of protecting public health.

The Commission also claims that the Italian measures at issue may likewise constitute a means of arbitrary discrimination contrary to Article 36 of the EEC Treaty. Although the measures are based on legislation which is applicable without distinction, they essentially affect imported fish. Even though the telegram of 14 October 1987 from the Italian Ministry of Health extended the health inspections to fish of national origin, it is clear that domestic production is subjected only to irregular checks, because the health authorities have not the necessary inspection capacity to check all fish marketed in Italy, whereas imports of fishery products are inspected systematically because such restrictions are much easier to apply in view of the limited number of customs clearance points.

In the Commission's view, the fact that inspections are more rigorous for imported than domestic products and that the difference in the way they are treated is not justified by objective factors relating to any major risks to public health from imported

fish as compared with domestic products is attributable to the Italian authorities' wish in fact to introduce protectionist practices, to discourage the importation of fish and encourage the domestic fishing industry, to support a sector in crisis or meet the demands of lobbies in the sector concerned.

The Commission claims, lastly, that the Italian inspection measures jeopardize the objectives underlying Regulation No 3796/81, which seeks to ensure the harmonious operation of the common organization of the market in fishery products, by unnecessarily controlling the flow of imports into Italian territory, thus causing serious disturbance to the European markets in fishery products and substantial damage to traders in that sector.

— In the second place, the Commission considers that the Italian Republic has infringed *Directive 83/643*, which, with a view to facilitating inspections and administrative formalities at frontiers, stipulates that inspections should be carried out by means of spot checks, except in duly justified circumstances.

The Italian Republic introduced systematic health inspections on consignments of fish from other Member States and from Norway in 1987 and continues to carry out such inspections, although such conduct is not justified on objective scientific grounds. The Italian Republic has also infringed Article 9 of the directive in so far as it failed to notify the Commission before introducing a new inspection and did not ensure that the measures taken to facilitate the crossing of frontiers were not rendered inoperative through the application of such new inspections. Lastly, even the Italian Republic's transposition of the directive is not exempt from criticism, since Ministerial Orders No 454 of 1988 and No 47 of 1990 specify that at least 10% of consignments must be inspected, a far higher proportion than would be covered by spot checks, and that the proportion may be increased if there is any doubt or if precautions need to be taken, thus opening the way to all kinds of abuse.

— Thirdly, the Commission argues that the Italian Republic has failed to comply with *Regulation No 1691/73*.

It claims, in particular, that Article 15(2) of the agreement annexed to that regulation has been infringed inasmuch as the Italian health inspection measures have the effect of unduly obstructing trade between Italy and Norway in the fishery products sector. Also, since Articles 13 and 20 of the agreement merely transpose the principle enshrined in Articles 30 and 36 of the EEC Treaty, they too have been infringed in the present case.

(c) On the basis of those arguments, the Commission concludes that, in order to comply with Community law, the Italian Republic should not only adopt a measure putting an end to the systematic inspection of imports of fish and fishery products from

other Member States and Norway but also amend its basic legislation, in particular Article 5 of Law No 283 of 1962, so that the sole presence of nematodes no longer constitutes contamination in fish, and Article 3 of Ministerial Order No 454 of 1988, as amended by Ministerial Order No 47 of 1990, so that the limits on inspections by means of spot checks are more reasonable than those laid down in the present ministerial order.

2. In its defence, the *Italian Government* contends that the Commission's application is without foundation.

(a) The Italian Government first rejects the Commission's allegation that the inspection measures at issue constitute protectionist practices.

It maintains that neither the Italian legislation nor its actual implementation give rise to any discrimination between domestic and imported products. Thus, the veterinary authorities' inspections of fresh and frozen fish and fishery products of Italian origin are carried out on a daily basis and cover all domestic production. The Commission itself has acknowledged that the Italian inspections for nematode larvae have been extended to all domestic fishery products.

(b) The Italian Government next states that, under Article 5 of Law No 283 of 1962, consignments of fish containing live or devitalized nematode larvae may not be marketed. The Commission is mistaken in supposing that, in the absence of Community legislation on fishery products infested with nematodes, the general principle enunciated in Article 6(5) of Regulation No 103/76, as amended, must apply.

In the present case, account must be taken of Council Directive 91/493/EEC of 22 July 1991 laying down, in greater detail, the health conditions for the production and the placing on the market of fishery products. Section V of Chapter IV of the Annex to that directive, which is entitled 'Conditions concerning parasites', states that

'1. During production and before they are released for human consumption, fish and fish products must be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible.

Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption.

...

2. The fish and fish products referred to in point 3 which are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than -20°C in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.

3. Fish and products subject to the conditions in point 2:

(a) fish to be consumed raw or almost raw, e. g. raw herring "maatje";

(b) the following species, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60°C:

— herring,

— mackerel,

— sprat,

— (wild) Atlantic and Pacific salmon;

(c) marinated and/or salted herring where this process is insufficient to destroy the larvae of nematodes'.

According to the Italian Government, it follows that the product must be free from visible parasites, alive or dead, and any parasites that are not visible on inspection must be neutralized. Consequently, no product in which nematode larvae are found should ever be marketed for human consumption, since dead larvae also infect the product and constitute grounds for withdrawing it from the market.

The Italian Government therefore considers that its legislation and the inspection measures carried out constitute advance implementation of Directive 91/493. Products containing nematode larvae, even devitalized, are stopped at the frontier not only because they are unhygienic but also because, in the light of the present still incomplete state of scientific knowledge, they are toxic to a not insignificant degree. The toxicity of the products increases in proportion to the quantity of devitalized nematodes and it is therefore reasonable to turn back the whole of a consignment that is only partly infested, since it cannot be inspected fish by fish.

It follows that Italy has not infringed Community law in any way. The product in question may comply with the rules of the producer State but that is not sufficient to make it marketable in another State also where, as in this case, Community legislation itself authorizes, or even imposes, stricter rules and, in any case, the inspections are justified by manifest requirements relating to the protection of public health. Moreover, the Federal Republic of Germany at least has adopted similar measures to those in force in Italy.

(c) The Italian Government also argues that it is wrong to claim that in practice the Italian inspection measures are capable of preventing the importation of fish from other

Member States and Norway, since only some consignments, which contained nematode larvae and were therefore unfit for human consumption, have been turned back.

Moreover, while inspections are normally required to be carried out by means of spot checks, the Italian Government considers that it is legitimate to step up inspections in cases where products arouse suspicions (see, in particular, Directive 83/643 and the judgment in Case 35/84 *Commission* v *Italy* [1986] ECR 545, paragraph 11). In this case, the Italian authorities had found that many consignments of fish did not comply with the Community legislation and they had therefore been turned back. However, the inspections had never been systematic and the instances cited by the Commission in its application are not significant.

The Italian Government therefore argues that the Italian measures are proportionate in relation to the objective of protecting public health and the Commission's suggestions to the effect that Italy should adopt alternative, less restrictive measures are not acceptable. Eating habits in Italy and the spread of new and different habits in that State make it unacceptable simply to prohibit the consumption of raw fish. Similarly, if the product in question is infected and dangerous, it is not enough merely to warn consumers. Moreover, Italy recognizes health certificates issued by the country of origin of the product, subject to the provisions of Directive 91/493, which specify that the presence of parasites that are visible or have obviously been removed renders the product unfit for human consumption.

3. In the reply, the *Commission* notes, first, that the Italian Republic offers practically no defence against the allegation that it has infringed Directive 83/643 and Regulation No 1691/73. Nor does the Italian Government challenge the scientific data cited by the Commission.

The Commission goes on to refute the arguments advanced by Italy in its defence.

(a) In the first place, it points out that although the contested measures are applicable without distinction, they primarily affect imported goods and therefore constitute a means of arbitrary discrimination contrary to Article 36 of the EEC Treaty.

(b) In the second place, it argues that Directive 91/493 was published after the application was lodged and covers much the same ground as the proposal for a Regulation of 22 February 1988, amended on 18 September 1989, cited by the Commission, and that Member States are not required to implement it until 1 January 1993. A directive cannot produce effects that are binding on the Member State to which it is addressed until the period prescribed for its transposition has expired (Case 148/78 *Ratti* [1979] ECR 1629, paragraph 43), besides which the Commission was not informed by the Italian Government that it had already transposed the directive.

In any case, even if Directive 91/493 does introduce changes, they relate only to the future. It cannot legitimate *ex post* conduct contrary to Community law, with the result that Italy has still failed to fulfil its obligations in respect to the past.

The Commission considers that the Italian Government is mistaken in referring to Chapter IV of the annex to that directive, which is concerned with 'special conditions for handling fishery products on shore' and therefore has nothing to do with the inspections at the frontier at issue in this case.

Moreover, the Italian Government's assertion that the directive specifies that infested products must be rejected is without foundation. According to Chapter IV, section V, point 1, of the annex to the directive, inspections are to relate only to visible parasites, whereas in biological terms nematode larvae of the 'anisakis' variety are regarded as invisible, and such inspections are in any case subject to Community rules and are to be carried out in on-shore establishments, not at the frontier. Points 2 and 3 of that section provide for certain types of fish to undergo a freezing process, a measure that the Commission had suggested in the present case.

Similarly, Article 3(1)(d) of Directive 91/493 provides for visual inspection, by way of sample, for the purpose of detecting any parasites that are visible.

Finally, Article 9 of Directive 91/493 states that Directive 89/662 is to apply to fishery products. But that directive abolishes inspections at frontiers and Article 3 thereof provides that health inspections are generally to be carried out in the State of origin of the goods.

(c) In the third place, the Commission argues that the Italian Government's contention that the inspections at issue are justified by the need to protect consumers' health is mistaken inasmuch as it presupposes a danger that does not exist in the present case and gives rise to protective measures that are entirely disproportionate.

4. In the rejoinder, the *Italian Government* points out that the Ministry of Health has adopted Circular No 10 of 11 March 1992, which contains instructions and recommendations on the presence of anisakis larvae in fish and was published in GURI 1992, No 62. That circular provides, in substance, as follows:

'— it is necessary to guarantee that the application of inspection controls is uniform and precise throughout the national territory;

— anisakis has not, as yet, shown any significant pathology in Italy;

— anisakis is dangerous if the larvae are alive but not if they are dead;

— anisakis primarily affects certain species of fish and the larvae generally lodge in the pleuro-peritoneal cavity of the fish when it is alive and move into the muscular tissue after it dies: "rapid gutting

may constitute an appropriate measure to prevent parasitosis in humans";

— it is recommended that gutting should be carried out in good time by fishermen and traders handling fresh fish;

— Directive 91/493 provides that, before they are released for human consumption, products must be subject "to a visual inspection, by way of sample, for the purpose of detecting any parasites that are visible"; if products are obviously infested with parasites, they may not be placed on the market for human consumption;

— the detailed rules for inspection are to be laid down by the Commission of the European Communities; pending such provisions, fresh or chilled fish, particularly fish that presents risks, must be subject to "spot checks on statistically representative samples, with visual inspection of the fish after the pleuroperitoneal cavity has been opened";

— any products presenting "a repulsive or disgusting appearance" must be destroyed; failing that, they must be cleansed by means of special treatment to ensure that larvae are devitalized;

— measures will be adopted to prevent the use of "preparations based on raw or practically raw fish" in public or collective catering and information to this effect should be disseminated through food education campaigns'.

The Italian Government therefore considers that there is no longer any reason to consider this case any further, and asks the Commission to consider withdrawing its application, particularly as its complaints relate mainly to the 1987/1988 period. It points out that the abovementioned circular has clarified the situation by defining the limits to which health inspections are subject. It confirms that Italy has never failed to fulfil its obligations under Community law because the inspections were always occasional and remained within acceptable overall limits, and consignments of fish were turned back only if they were contaminated.

IV — The Commission's reply to the question put by the Court

The Court asked the Commission to reply in writing to the following question:

'The Italian Government stated in the course of the written procedure that at least one other Member State had legislation similar to its own and the Commission is therefore invited to provide a brief summary of the various Member States' rules on the health inspection of fish.'

In answer to this question, the Commission pointed out that many of the national rules were general in nature, relating to all foodstuffs, and that none of them at present

required fish to undergo an inspection at the frontier of the kind provided for in the Italian legislation at issue in this case.

— In Belgium, it is prohibited to import, market, process or hold fish that has not been marked following a health check, expert examination or health inspection. In addition to verifying the state of health, freshness, integrity and temperature of the fish, the expert may, if he deems it to be necessary, carry out a chemical, parasitological, microbiological or other examination of the product. Imported consignments of fish must be accompanied by a health certificate in good and due form and must be carried in special packaging bearing a mark to certify that the contents have been inspected in the country of origin; such consignments are also subject to a health inspection at the place of destination. The Belgian legislation does not include any specific provisions on the presence of parasites in fish.

— Denmark prohibits the sale, preservation, processing and transport of poor quality fish. If the authorities responsible for inspection consider that the fish is unfit for human consumption, they must affix a label provided for the purpose to the packaging of the product in question. These rules apply equally to imported products. There are no special rules on infestation of fish with parasites.

— Under the French legislation, all imported foodstuffs are subject to health inspection and quality control by officers of the specialist veterinary services and must be accompanied by documents certifying that they comply with the French rules; foodstuffs that do not comply are turned back and any products that are found to be contaminated or toxic, or present a risk to health, are seized and destroyed. The importation of consignments of fish, in particular, is subject to a health inspection and the production of a health certificate issued in the country of origin of the product; the health inspection includes taking samples, which are analysed in a laboratory. There are no special rules on parasites. The Commission notes that this legislation has never presented any unjustified obstacle to goods crossing the frontier.

— In Germany, the marketing of fish infested with parasites is prohibited and any parts of fishery products infested with live or dead nematodes must be removed or destroyed. The marketing of fish that has not been gutted or that contains nematodes is liable to prosecution, except in the case of herring, which may be sold whole provided that the presence of nematodes, if any, is declared. Provision is made for health analyses to be carried out on samples from consignments intended for the German market. If the analysis, by means of visual inspection on a light table or chemical examination, reveals the presence of more than one nematode per kilogram in the first case or more than three per kilogram in the second, the product is deemed to be infested and the consignment must be rejected. These rules apply equally to imported fish.

The Commission states that the frontier control problems associated with this legislation

obliged it to institute infringement proceedings against the Federal Republic of Germany. However, a satisfactory solution was found in 1991, inasmuch as the methods and criteria employed for the analyses were revised so as not to hinder the free movement of goods, action by the health authorities was confined to cases where live nematodes were found, and the labelling and selective classification of fish were applied in such a way that it had been possible to close the infringement procedure.

— Under the Greek legislation, the importation and marketing of fish are prohibited, *inter alia*, if the fish is found to contain worms. Infested consignments of fish are confiscated, destroyed or, where appropriate, used for animal feed.

— The Commission reports that it has no relevant information on the legislation governing health inspections of fish in Ireland; it can be stated, however, that there are no specific rules on the presence of nematodes in fish that would hinder the free movement of goods.

— In Luxembourg, there is no specific legislation on the presence of parasites in fish.

— The Netherlands health legislation has never hindered the importation of fish from other Member States. A 1984 order requires herring to be frozen at -20°C to destroy any parasites. Any risk of ingesting live larvae when consuming 'maatjes' is thus ruled out.

— In Portugal, the legislation on health inspection of fish intended for human consumption provides for immediate withdrawal of any products that are 'repugnant', including any containing parasites. Health inspectors may also order laboratory analyses of samples taken from the consignments inspected. Exceptionally thorough health checks are carried out if more than 5% of the samples are found to contain parasites. These rules apply equally to imported products.

— In the United Kingdom, the Imported Food Regulations establish criteria for the health inspection of all imported foodstuffs and specify that products unfit for human consumption are to be destroyed by the competent veterinary authorities after undergoing a special inspection procedure. There are, however, no specific rules on fishery products infested with nematodes.

— The Spanish legislation establishes a system of classification of fish and fishery products under which category 'D' comprises products containing high-risk pathogenic agents, which must be destroyed immediately. Imported products must comply with the Spanish legislation and be accompanied by a document certifying that the fish has undergone a health inspection in the country of origin. The Spanish health authorities are

responsible for monitoring and ensuring compliance with these rules. There is no legislation relating specifically to nematodes.

V — Oral procedure

At the hearing on 12 January 1993, the Advocate General asked the Commission whether, in the light of the wording of Article 2 of the Agreement between the EEC and Norway, fishery products were not excluded from the scope of that agreement. The President of the Court allowed the Commission two weeks to answer the question and the Italian Republic two weeks thereafter to submit its observations on the reply.

1. The *Commission's* reply was that, although agricultural products are excluded from the favourable customs treatment provided for under the agreement, nevertheless Article 15, and particularly paragraph 2 thereof, requires the Contracting Parties to foster the harmonious development of trade in agricultural products and not to introduce in veterinary, health and plant health matters any new measures that have the effect of unduly obstructing trade. In those circumstances, the Commission maintained that it was justified in claiming in the present case that the Italian Republic had failed to comply with Article 15(2) of the agreement with Norway.

2. The *Italian Government*, commenting on the Commission's reply, said that the agreement did not apply to trade in agricultural products and that the Contracting Parties merely declared their intention to foster the development of trade in such products and to endeavour to overcome any difficulties that might arise in that connection: such provisions could not provide grounds for an action against a Member State for failure to fulfil obligations. Moreover, Article 15(2), cited by the Commission, referred only to 'new measures' and the Italian authorities had not adopted any such measures in the present case. In those circumstances, the Italian Government considered that the action was, in particular, without foundation in respect of imports of Norwegian fish.

F. A. Schockweiler
Judge-Rapporteur